

of procedures or activities, we are stating that compliance with the regulation requires that you adopt, at the minimum, the procedures or activities listed in the regulation. Therefore, when we state “includes, but is not limited to,” we mean that the list of procedures or activities following the “includes” statement is a list of requirements.

## 2. What Personnel Qualification Requirements Apply? (Proposed § 111.12)

Proposed § 111.12 would establish basic qualification requirements for employees. Proposed § 111.12(a)(1) would require that you have qualified employees to manufacture, package, or hold dietary ingredients or dietary supplements. We are not proposing a general standard for determining how many employees are necessary, but there should be enough to manufacture, package, or hold dietary ingredients or dietary supplements consistent with these proposed CGMPs. A one-person operation is not precluded provided that one person is sufficient to achieve, maintain, and document CGMPs. However, general manufacturing practice suggests the need for a minimum of two persons, the first to perform the work and a second person to check the work performed to ensure that a manufacturing deviation or an unanticipated occurrence is not overlooked. However, we leave the determination of the actual number of employees necessary to your discretion. As stated previously, we invite comment on whether there is a minimum number of employees needed to manufacture dietary ingredients or dietary supplements.

Proposed § 111.12(a)(2) would require that each person engaged in manufacturing, packaging, or holding must have the training and experience to perform the person's duties. Training is necessary to ensure that employees know how to correctly and fully perform the operations in question and to ensure that the employees are competent to produce an unadulterated product. The extent and frequency of the training is left to the manufacturer's discretion. The extent and frequency of training needed for your employees will depend on the scope of the employee's activities and experience. For example, training may be necessary when you hire new employees, when employees engage in new activities, when your physical plant implements new manufacturing practices, or when you add new equipment or new processes to manufacturing. For example, an employee responsible for measuring

ingredients during batch production should have sufficient training or expertise to perform those functions. If that employee does not know how to measure correctly, the employee may add too much of an active ingredient, which may cause the product to be adulterated. Thus, proposed § 111.12 would establish requirements for your employees.

We invite comment on whether we should require, in a final rule, a requirement that you document and keep records regarding each employee's training. We believe that the records, if required, should show the content and date of the training. Such records may be useful in determining whether an employee has received the training necessary to perform his or her duties. We invite comment on not only whether such records should be required in a final rule, but also what types of information such records should contain.

You may use consultants to advise you on any aspect of the manufacture, packaging, or holding of dietary ingredients or dietary supplements. Any consultant you use should be qualified by training and experience to provide the advice they give to you. We invite comment on whether we should require, in a final rule, that you document each consultant's name, address, and qualifications and include a description of the services that the consultant provided. Such records may assist you in knowing who to contact and where to contact him or her if questions arise concerning the advice given.

A comment to the ANPRM suggested that the employee qualification requirements in the industry outline should, in part, state that “proper education, training, or experience” is required instead of “proper education, training, and experience” is required (emphasis added).

We disagree with the use of “or” instead of “and.” We omitted the term “proper education” because “training” may be considered a form of “education.” However, the proposed rule uses the conjunction “and” because, while some might consider “experience” to be a form of “training,” most consider “experience” to be knowledge that a person gains over time as he or she becomes increasingly familiar with a particular action or piece of equipment.

Training, however, may not just include on-the-job training, but may include some type of educational experience derived from attending classes or lectures or some other formal instruction on a particular subject. Some positions not only require the employee

to have experience or training on the job, but also require that the employee have the appropriate educational background, for example, to understand the significance of using a particular test method or understanding the significance of a processing deviation and how to respond to such deviation. The word “and” includes situations where on-the-job training may be adequate and also situations where educational training may be required. Therefore, proposed § 111.12(a)(2) refers to “training and experience.”

## 3. What Supervisor Requirements Apply? (Proposed § 111.13)

Proposed § 111.13 would establish general supervision requirements and is similar to a provision that appeared in the industry-drafted outline. Proposed § 111.13(a) would require that you clearly assign to qualified supervisory personnel the responsibility for ensuring that all CGMP requirements in part 111 are met. You should assign an adequate number of qualified personnel to supervise the manufacturing, packaging, or holding of dietary ingredients and dietary supplements. We are not proposing a general standard for determining how many supervisors are necessary and a one-person operation is not precluded provided that one person is sufficient to supervise CGMPs. As stated previously, we invite comment on whether there is a minimum number of qualified personnel to supervise the manufacturing, packaging, or holding of dietary ingredients or dietary supplements. Proposed § 111.13(b) would require you and your supervisors to be qualified by training and experience to supervise.

Making supervisors responsible for compliance with the regulations would be an important step in manufacturing, packaging, and holding dietary ingredients and dietary supplements under conditions that will not cause adulteration and misbranding. We believe that clearly designating compliance responsibilities to individuals increases the likelihood of compliance with the regulations.

One comment to the ANPRM questioned why supervisory personnel must be “qualified” when the food CGMP regulations require supervisory personnel to be “competent” (see § 110.10(d)).

We consider the terms to be equivalent in this case. The *Webster's II New Riverside University Dictionary* defines competent as “able to perform as required: competent” and further defines “qualified” as “having met the requirements for a specific position or